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News Release

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CONFIDENCE Phase II study results presented at 62nd ERA Congress:

Simultaneous treatment start with Finerenone and SGLT-2-inhibitor demonstrated positive data in patients with CKD associated with type 2 diabetes

- Results of the Phase II study CONFIDENCE demonstrate that simultaneous initiation of finerenone and an SGLT-2-inhibitor (SGLT-2i) led to significant reductions in urine albumin-to-creatinine ratio (UACR) versus either agent alone in patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)
- These benefits were observed as early as 14 days after treatment initiation, supporting the potential of simultaneous initiation of finerenone and an SGLTI-2i
- UACR is an early indicator of kidney damage, an important prognostic marker of kidney disease progression, and a predictor of adverse cardiovascular outcomes

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Berlin, June 5, 2025 – Bayer announced today results of the Phase II CONFIDENCE study, demonstrating that simultaneous initiation of finerenone (Kerendia™) and the SGLT-2-inhibitor (SGLT-2i) empagliflozin led to a significantly greater reduction in urine albumin-to-creatinine ratio (UACR) in adults with chronic kidney disease (CKD) associated with type 2 diabetes (T2D) than with either treatment alone. The findings were presented at the 62nd European Renal Association (ERA) Congress 2025 and simultaneously published in the *New England Journal of Medicine*.

The CONFIDENCE study showed that simultaneous initiation with finerenone and empagliflozin in patients with CKD associated with T2D led to an early and additive reduction in UACR from baseline of 52% at Day 180. This was a 29% and 32% greater relative reduction in UACR from baseline to Day 180 compared to finerenone alone and empagliflozin alone, respectively. Notably, a reduction of more than 30% in UACR was observed within 14 days of starting both treatments simultaneously – a threshold

recommended by the American Diabetes Association (ADA) to slow kidney disease progression in patients with CKD*. Almost 3 out of 4 patients achieved this threshold of a 30% reduction in UACR versus baseline – 20% more than with either treatment alone. The safety profile of simultaneous initiation of finerenone and SGLT-2i was consistent with that of either agent alone, and treatment benefits were seen across all prespecified subgroups enrolled in the study, across a broad spectrum of patient populations with a high comorbidity burden.

“The CONFIDENCE study delivers clinical evidence that simultaneous initiation of finerenone and empagliflozin led to an early and additive reduction in UACR of 52% in patients with chronic kidney disease and type 2 diabetes, which was significantly greater than with either treatment alone,” said Rajiv Agarwal, MD, Professor Emeritus of Medicine, Indiana University School of Medicine and VA Medical Centre, Indianapolis, USA and Chair of the study’s Steering Committee. “Given that UACR is an important mediator of kidney and cardiovascular outcomes, these findings provide key insights to clinicians when considering how to optimize disease management, supporting the early combined use of finerenone and an SGLT-2 inhibitor for a positive impact on patient outcomes.”

Finerenone, a non-steroidal, selective mineralocorticoid receptor (MR) antagonist, has been investigated in a broad patient population with CKD (stages 1-4) associated with T2D across two completed and published Phase III studies, FIDELIO-DKD and FIGARO-DKD, which evaluated the effects of finerenone versus placebo on top of standard of care on both renal and cardiovascular outcomes. Patients on background therapy with an SGLT2-inhibitor were allowed in those studies. Data from FIDELITY, a prespecified pooled analysis of these Phase III studies, confirm that early albuminuria (UACR) reduction in patients with CKD associated with T2D mediated a large proportion of the treatment effect of finerenone in slowing CKD progression.

“The CONFIDENCE data mark an important milestone in our mission to improve care for people living with chronic kidney disease associated with type 2 diabetes,” said Dr. Michael Devoy, Chief Medical Officer at Bayer’s Pharmaceuticals Division. “The findings suggest that a proactive simultaneous initiation can deliver a substantial early and additive UACR reduction, which is associated with kidney and cardiovascular protection. We are excited to share these important results with physicians, as they demonstrate that

early combined use of finerenone and an SGLT2-inhibitor has the potential to improve long-term outcomes for millions of patients worldwide."

Diabetes continues to be a substantial public health issue, with an estimated 462 million people globally affected by T2D alone. Approximately 40% of people with T2D go on to develop CKD, highlighting a significant unmet medical need for therapies that can better protect kidney function and slow disease progression.

About the CONFIDENCE study

The CONFIDENCE (**CO**mbinatio**N** effect of **FI**nerenone an**D** **E**mpagliflozi**N** in participants with **C**KD and T2D using an UACR **E**ndpoint) study was a randomized, double-blind, double-dummy, multicenter, three-arm, parallel-group treatment, Phase II study. The primary objective of the study was to determine whether the simultaneous initiation and combined use of finerenone and empagliflozin would be superior to either treatment alone in reducing UACR in patients with CKD and T2D. The primary endpoint was the relative change in UACR from baseline to Day 180 for the combination therapy group compared to the monotherapy groups. The CONFIDENCE study randomized 818 patients in a 1:1:1 ratio, stratified by estimated glomerular filtration rate (eGFR) and UACR at screening. Patients received either finerenone (10 or 20 mg once daily) and empagliflozin (10 mg), finerenone (10 or 20 mg) and matching placebo, or empagliflozin (10 mg) and matching placebo.

About Kerendia™ / Firialta™ (finerenone)

Kerendia™ and Firialta™ are globally protected trademarks for finerenone. Finerenone is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist that has been shown to block harmful effects of MR overactivation. MR overactivation contributes to chronic kidney disease (CKD) progression and cardiovascular damage which can be driven by metabolic, hemodynamic, as well as inflammatory and fibrotic factors.

Finerenone is marketed as Kerendia™ or, in some countries, as Firialta™, and approved for the treatment of adult patients with CKD associated with type 2 diabetes (T2D) in more than 90 countries worldwide, including in China, Europe, Japan, and the U.S.

The clinical study program with finerenone, FINEOVATE, currently comprises ten Phase III studies with dedicated programs in HF and CKD respectively. The MOONRAKER program includes the completed Phase III study FINEARTS-HF, as well as the ongoing

collaborative, investigator-sponsored studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF. The THUNDERBALL CKD program consists of the completed Phase III studies FIDELIO-DKD and FIGARO-DKD and the Phase II study CONFIDENCE; as well as the ongoing Phase III studies FIND-CKD, FIONA, FIONA-OLE, and FINE-ONE.

About Bayer's Commitment in Cardiovascular and Kidney Diseases
Bayer is a leader in the area of cardiology and is advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer is working on new treatment approaches for cardiovascular and kidney diseases with high unmet medical needs. The strategy is to unlock the strong potential of the future CV market by transforming Bayer's portfolio into precision cardiology, addressing the high disease burden, and driving long-term growth. Bayer's portfolio already includes several innovative products and compounds in various stages of preclinical and clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cardiovascular diseases are treated.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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de (2025-0103E)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.